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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,199	06/13/2007	Zhao Yi Wang	180.00120101	4302

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EXAMINER	
SHAFER, SHULAMITH H	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,199	WANG, ZHAO YI	
	Examiner	Art Unit	
	SHULAMITH H. SHAFER	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *17-28 and 39-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,29-38 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11 July 2007,22 October 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, And/Or Claims:

Restriction Requirement:

Applicant's election, with traverse of Group I, claims 1-16, 29-35 (in part), 36-38 and 52, drawn to an isolated antibody which binds to an amino acid sequence of SEQ ID NO:1, a method for making said antibody, and a method of detecting a polypeptide comprising contacting a cell with an antibody which binds to an amino acid sequence of SEQ ID NO:1 and a kit comprising said antibody, in the reply filed on 30 June 2008 is acknowledged. The grounds for the traversal are (1) the inventions as claimed can be evaluated in one search without placing undue burden on the Examiner; And (2) the claims of Group I and V are both directed to a method for using the product, therefore the claims of Group V should be considered to have unity of invention.

Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons:

In response to (1): The instant application is a 35 U.S.C. § 371 filing, and MPEP § 1893.03(d), which describes restriction practice for applications filed under this statute states the following: "Examiners are reminded that unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. § 371...When making a lack of unity of invention requirement, the examiner must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single inventive concept) specifically describing the unique special technical feature in each group". The Examiner is not required to demonstrate an undue search burden.

In response to (2): 37 CFR 1.475,(d) states:

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

Thus, one invention of each category is to be considered. The first method of use mentioned in the claims is a method for detecting a polypeptide using an antibody.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-52 are pending in the instant application. Claims 17-28 and 39-51 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-16, 29-38, directed to a method for detecting a polypeptide utilizing an antibody and 52 are under consideration.

Information Disclosure Statement:

The Information Disclosure statements (IDS), submitted on 22 October 2007, has been considered. The signed copy is attached.

The information disclosure statement filed 11 July 2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the 5th reference on page 9 was not found among the submissions of the instant application; it has been lined through and not considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Objections

Claims:

Claim 12 is objected to because of the following informalities: there is a grammatical error in the claim: "isolating antibody". The claim should be amended to read "isolating the antibody".

Rejections

35 U.S.C. § 112, Second Paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 14, 16, 29-38, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis for the recitation of "immunogenic subunit" in claim 13. Thus, the metes and bounds of the claim cannot be determined. Amendment of the claim to read "immunogenic fragment" would be remedial.

Claim 14 is vague and indefinite in reciting "making a monoclonal-antibody producing hybridoma using the cell". Making a hybridoma is not a method of isolation.

Claim 29, an independent claim of the instant invention, is an incomplete method claim. To be complete, a method claim must state a goal in the preamble of the claim, and conclude having achieved that goal. Claim 29 is directed to a method of detecting a polypeptide. However, the method steps, as recited, are insufficient to accomplish the goal stated in the preamble. The method steps recite "analyzing". It is unclear how this step is to be performed, since "analyzing" is considered a mental or cognitive activity. Thus, it is unclear if carrying out the method steps would result in accomplishing the goal set forth in the preamble.

Furthermore, Claim 29 is vague and indefinite in reciting "ER-α36" and "ER-α36 activity". The claim identifies the protein of interest as "ER-α36" which fails to unambiguously define said protein. The claim should present clearly identifying characteristics of "ER-α36" . While the name itself may identify some activity associated with the protein, there is nothing in the claim that distinctly identifies the protein. Others in the field may isolate the same protein and give it an entirely different name or give the same name to a different protein. Applicant should particularly point out definitive characteristics associated with the protein. Describing biochemical

molecules by a particular name given to the protein by various workers in the field fails to distinctly identify what the protein is. Thus "ER-α36" is not sufficient to identify the claimed invention, one of skill in the art would not be able to determine what molecules are encompassed.

Additionally, the claim is indefinite in reciting "ER-α36 activity". There is no limiting definition of "ER-α36 activity" in the specification [see paragraph 0043 of PGPUB 20070258895, the PGPUB of the instant invention]; thus, the metes and bounds of the claim cannot be determined.

Claim 30 is vague and indefinite in reciting "wherein the cell is *ex vivo*. It is unclear how "providing a cell", as recited in 29, could be anything *but ex vivo*.

Claim 33 is vague and indefinite in reciting "wherein the cell is *in vivo*. Claim 30, the claim from which 33 depends, recites "providing a cell"; it is unclear how one can "provide a cell" if the cell is *in vivo*.

Claim 52 is rejected under 35 U.S.C. 112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 52 is considered indefinite because a kit, by definition, must contain 2 or more elements and the interrelationships between the elements must be explicitly stated (see In re Venezia 530 F.2d 956 CCPA 1975).

The remaining claims are included in this rejection as dependent upon rejected claims.

35 U.S.C. § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosen et al. (USPGPUB 2007/0015271, the '271 document, filed 27 April 2003).

The '271 document teaches a human sequence, SEQ ID NO:5141, a 111 amino acid peptide comprising a 6 amino acid fragment that is 100% identical to amino acids 11-16 of SEQ ID NO:1 (see results in SCORE and alignment below).

US 20070015271

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SQ   Sequence 111 AA;

  Query Match             22.2%;  Score 6;  DB 12;  Length 111;
  Best Local Similarity   100.0%;  Pred. No. 2.4e+02;
  Matches    6;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          11 ILNLHP 16
               ||||||
Db          90 ILNLHP 95
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As stated above, (see rejection under 35 USC 112, 2nd paragraph), The Claims recite "an isolated antibody that specifically binds to an amino acid sequence depicted at SEQ ID NO:1..... and immunogenic fragments thereof". This phrase encompasses an antibody that binds to a protein comprising the sequence of SEQ ID NO:1 or any portion of SEQ ID NO:1.

The '271271 document teaches antibodies to the polypeptides taught in the referenced document, which includes the polypeptide of SEQ ID NO:5141 [paragraph 0278]. This teaching would anticipate the limitations of Claim 1, as an antibody which binds to amino acids 90-95 of SEQ ID NO:5141 of the referenced document would also bind to SEQ ID NO:1 of the instant invention; an antibody to a fragment of a polypeptide that is 100% identical to amino acids 11-16 would also bind a fragment comprising amino acids 13-27 of SEQ ID NO:1, thereby anticipating the limitations of claim 9. The reference teaches the antibodies may include polyclonal, monoclonal antibodies or

humanized antibodies [paragraph 0337], thus anticipating the limitations of claims 2, 3. and 4. The '271 document teaches antibody derivatives that are modified by covalent attachment of any type of molecule to the antibody [paragraph 0347], thereby anticipating the limitations of claim 5. The antibodies may be conjugated to a diagnostic or therapeutic agent; detection can be facilitated by coupling the antibody to a detectable substance. Among the detectable substances taught by the reference are flourescent materials. Thus, limitations of claims 7 and 8 are anticipated. The antibody may be conjugated to a therapeutic moiety such as a cytotoxin; examples listed include chemotherapeutic agents such as antimetabolites, alkylating agents, and antimitotic agents (chemotherapeutic agents) [paragraph 0389], thereby anticipating the limitations of claim 6. The reference teaches methods of treatment comprising administration of an effective amount of the antibody as a pharmaceutical composition [paragraph 0458], thereby anticipating the limitations of claims 10 and 11. The '271 document teaches inducing antibodies by administering antigenic fragments (immunogenic epitopes) to an animal [paragraph 0283] and subsequently purifying the induced antibody [paragraph 0383]. The antibodies can be fused to heterologous polypeptide sequences (carrier molecules) to facilitate purification [paragraph 0383], thus anticipating the limitations of claims 12, 13 and 15. The reference teaches method of generating monoclonal antibodies comprising making and culturing a hybridoma cell secreting an antibody of the invention [paragraphs 0350-0351]; therefore the limitations of claims 14 and 16 are anticipated. Finally, the '271 document teaches kits comprising the antibody of the invention in one or more containers [paragraph 0481], thereby anticipating the limitations of claim 52.

Thus, the '271 document anticipates all the limitations of claims 1-16 and 52.

Claims 29-38 are free of the prior art.

Conclusion:

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHULAMITH H. SHAFER whose telephone number is (571)272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao, Ph.D. can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/ Ph.D.
Primary Examiner, Art Unit 1647

/S. H. S./
Examiner, Art Unit 1647